REMARKS

Claims 26-46 are presently pending in the case. Claims 26, 29, 30, 33, 35, 37-39, 42 and 43 have been amended. Claims 44-50 have been added. The new claims and amendments are supported by the specification and claims as originally filed. For example, see page 9, lines 3-19 and page 7, lines 29-31 of the specification as originally filed.

Reconsideration of the present case in view of the above amendments and the remarks herein is requested.

Claim rejections under 35 USC §102

The Examiner rejected claims 31-33 and 39-42 under 35 USC §102(e) as being anticipated by U.S. Patent 5,506,203 to Backstrom et al (hereinafter Backstrom et al). The rejection is traversed.

Backstrom et al does not qualify as prior art against Applicant's claims. The present Application is a continuation of Application Serial No. 08/668,036 which is a divisional of Application Serial No. 08/383,475 which is a continuation-in-part of Application Serial No. 08/207,472 which was filed on March 7, 1994. Since present claims 31-33 and 39-42 are supported by the 08/207,472 application (see, for example, page 4 line 13 through page 5 line 29 and page 17 line 18 through page 20 line 22), they are entitled to an effective U.S. filing date of March 7, 1994. Backstrom et al does not have a U.S. filing date before March 7, 1994. Therefore, Backstrom et al does not qualify as prior art under 35 U.S.C. §102(e). Note that Backstrom et al's Swedish filings are of no moment in this regard, see In re Hilmer, 359 F.2d 859, 149 USPQ 480 (CCPA 1966).

Applicant requests withdrawal of the rejection of claims 31-33 and 39-24 under 35 U.S.C. §102(e).

Claim rejections under 35 USC 103(a)

The Examiner rejected claims 26-43 under 35 USC §103(a) as being unpatentable over Backstrom et al. The rejection is traversed.

Backstrom et al does not qualify as prior art for the purpose of a rejection under 35 USC §103(a). In order for a reference to qualify as prior art under 35 USC §103(a) it must qualify under one of the subsections of 35 USC §102. Backstrom et al does not so qualify, as discussed above. Accordingly, Backstrom et al may not be relied on in making a rejection under 35 USC §103(a), and Applicant requests withdrawal of the rejections.

The Examiner rejected claims 28-30, 34, 36, 38 and 43 under 35 USC §103(a) as being unpatentable over Backstrom et al in view of Japanese Patent 56 138 110. The rejection is traversed.

Backstrom et al does not qualify as prior art against Applicant's claims when combined with the Japanese patent, either. Applicant requests withdrawal of the rejections.

Claim rejections under doctrine of Double Patenting - the '705 Application

The Examiner provisionally rejected claims 31-34 and 39-43 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 28, 29, 32-33, 35-49 and 51-58 of U.S. Patent Application No. 10/245,705 (hereinafter the '705 Application).

I. Independent claim 31 is allowable over the '705 Application

The Examiner's improper rejection of claim 31 on the ground of nonstatutory

obviousness-type double patenting as being unpatentable over the claims of the '705 Application should be withdrawn.

Nonstatutory double patenting is a judicially-created doctrine seeking to prevent the unjustified timewise extension of a patent. A nonstatutory obviousness-type double patenting rejection of claim 31 would be appropriate only if claim 31 is either anticipated by or would have been obvious over a claim in the '705 Application. Neither is the case here, as will be explained.

A. Claim 31 vis-à-vis independent claim 28 of the '705 Application

A side-by-side tabular comparison of Applicant's claim 31 and independent claim 28 and the claims depending therefrom in the '705 Application is provided:

Applicant's claim	'705 Application
31. An **insulin** composition for pulmonary delivery, said composition comprising a dry powder of individual particles which include **insulin present at from 20% to 80% by weight** in a pharmaceutical carrier material, wherein the particles have an average size below 10 μm. (Emphasis added to highlight limitations not recited in compared claims).	28. A therapeutic composition in dry powder form comprising a therapeutically effective amount of a pharmaceutical agent in combination with a pharmaceutical carrier, wherein said carrier is a bulking agent in the form of an amorphous powder, and wherein said composition is a powder suitable for administration by inhalation, wherein said powder comprises particles having a diameter less than about 10 μm and said pharmaceutical agent is available in said particles for rapid dissolution in fluid.

	29. The composition according to claim 28, wherein said powder comprises particles having a diameter of between 1 and 5 μm.
	43. The composition according to claim 28, wherein said carrier is a carbohydrate.
	44. The composition according to claim 28, wherein the pharmaceutically acceptable carrier is a monosaccharide selected from the group consisting of galactose, D-mannose, and sorbose.
	45. The composition according to claim 28, wherein the pharmaceutically acceptable carrier is a disaccharide selected from the group consisting of lactose and trehalose.
	46. The composition according to claim 28, wherein the pharmaceutically acceptable carrier is a disaccharide selected from the group consisting of raffinose, maltodextrins and dextran.
	47. The composition according to claim 28, wherein said carrier is an alditol selected from the group consisting of mannitol and xylitol.
	48. The composition according to claim 28, wherein the composition is spray dried.
	49. The composition according to claim 28, wherein the carrier is combined with the pharmaceutical agent prior to being spray-dried.

No claim in the claim set consisting of claims 28, 29 and 43-49 of the '705 Application anticipates Applicant's claim 31. As can be seen from the above table, Applicant's claim 31 recites features that are not present in a claim in the above claim set. For example, Applicant's claim 31 recites an "insulin composition" and further recites "insulin present at from 20% to 80% by weight in a pharmaceutical carrier material." Independent claim 28 and the claims depending therefrom in the '705 Application fail to recite at least these features and therefore fail to anticipate claim 31.

In addition, no claim in the claim set consisting of claims 28, 29 and 43-49 of the '705 Application renders Applicant's claim 31 unpatentable as being obvious. A double patenting rejection of the obviousness type when not based on an anticipation rationale is "analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. §103." *In re Braithwaite*, 379 F.2d 594. The obviousness or nonobviousness analysis therefore parallels the analysis of a 35 U.S.C. §103 obviousness determination. *In re Braat*, 937 F.2d 589; *In re Longi*, 759 F.2d 887.

Applying the 35 U.S.C. §103 analysis, Applicant's claim 31 is not rendered unpatentable by the invention defined in any of the claims in the claim set consisting of claims 28, 29 and 43-49 in the '705 Application. Claim 31 recites an insulin composition and further recites that the insulin is present at from 20% to 80% by weight in a pharmaceutical carrier material. These features are not present in the invention defined by claims 28, 29 and 43-49 of the '705 Application. Although the Examiner asserts that a skilled artisan would have been motivated to change the amount of insulin, Applicant respectfully submits that the Examiner has failed to provide any support or rationale for that position. In contrast with the assertions by the Examiner, the claims of the '705 Application do not indicate that the amount of insulin is a result-effective variable. Even if there were motivation to optimize the amount of insulin, the Examiner has failed to provide any reasoning as to why a skilled artisan would have chosen the presently recited amount of insulin. Because the claims of the '705 Application recite no ranges, there are a myriad of possibilities. Thus, the Examiner has failed to establish a prima

facie case of obviousness.

Since insulin and the amount of insulin are not present and since the Examiner has provided no basis for making a modification that would result in the invention defined by Applicant's claim 31, there is no prima facie case established. Also, when considering whether the invention defined by a claim of an application is an obvious variation of a claim in a patent, the disclosure of the patent may not be used as prior art. *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272. Thus, it follows that in determining whether Applicant's claim 31 would have been an obvious variation of the invention defined in the '705 Application, the disclosure of the '705 Application may not be used as prior art.

Furthermore, even if there was a prima facie case of obviousness, such case would be overcome by the unexpected results of the present invention. In this regard, Applicant has unexpectedly found that the present invention provides for the pulmonary delivery of insulin in a way that can be an effective alternative to administration by subcutaneous injection, as discussed for example on page 4 lines 32-37 of the specification.

For at least these reasons, Applicant's claim 31 is not properly rejectable under obviousness-type double patenting as being unpatentable over the claim set consisting of claims 28, 29 and 43-49 of the '705 Application. The modification proposed by the Examiner is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. There is no evidence to suggest that this is a situation where the ordinary artisan could have modified the invention defined by claims 28, 29 and 43-49 of the '705 Application in a manner that would result in the invention of Applicant's claim 31, and there is no evidence to suggest the artisan would have seen the benefit in doing so. Furthermore, Applicant has unexpectedly found that the invention as defined in Applicant's claim 31 provides for the pulmonary delivery of insulin in a way that can be an effective alternative to administration by subcutaneous injection, as discussed for example on page 4 lines 32-37 in the specification. Thus,

Applicant's claim 31 is allowable over claims 28, 29, and 43-49 of the '705 Application.

B. Claim 31 vis-à-vis independent claim 32 of the '705 Application

A side-by-side tabular comparison of Applicant's claim 31 and independent claim 32 and the claims depending therefrom in the '705 Application is provided:

Applicant's claim	'705 Application
31. An **insulin** composition for pulmonary delivery, said composition comprising a dry powder of individual particles which include **insulin present at from 20% to 80% by weight** in a pharmaceutical carrier material, wherein the particles have an average size below 10 μm. (Emphasis added to highlight limitations not recited in compared claims).	32. A therapeutic composition in dry powder form comprising a therapeutically effective amount of a pharmaceutical agent in combination with a pharmaceutically acceptable carrier, wherein said carrier is a bulking agent in the form of an amorphous powder, said therapeutic composition is a powder suitable for administration by inhalation, the pharmaceutical agent is selected from the group consisting of insulin, interleukin-1 receptor, parathyroid hormone (PTH-34), alpha-1-antitrypsin, calcitonin, low molecular weight heparin, interferon and nucleic acids, and said powder comprises particles having a diameter less than about 10 μm and said pharmaceutical agent is available in said particles for rapid dissolution in fluid.
	51. The composition according to claim 32, wherein said powder comprises particles having a diameter of between 1 and 5 μm.

	52. The composition according to claim 32, wherein said carrier is a carbohydrate.
	53. The composition according to claim 32, wherein the pharmaceutically acceptable carrier is a monosaccharide selected from the group consisting of galactose, D-mannose, and sorbose.
	54. The composition according to claim 32, wherein the pharmaceutically acceptable carrier is a disaccharide selected from the group consisting of lactose and trehalose.
	55. The composition according to claim 32, wherein the pharmaceutically acceptable carrier is a disaccharide selected from the group consisting of raffinose, maltodextrins and dextran.
	56. The composition according to claim 32, wherein said carrier is an alditol selected from the group consisting of mannitol and xylitol.
	57. The composition according to claim 32, wherein the composition is spray dried.
	58. The composition according to claim 32, wherein the carrier is combined with the pharmaceutical agent prior to being spray-dried.

No claim in the claim set consisting of claims 32 and 51-58 of the '705 Application anticipates Applicant's claim 31. As can be seen from the above table,

Applicant's claim 31 recites features that are not present in a claim in the claim set. For example, Applicant's claim 31 recites "insulin present at from 20% to 80% by weight in a pharmaceutical carrier material." Independent claim 32 and the claims depending therefrom in the '705 Application fail to recite at least this feature and therefore fail to anticipate claim 31.

In addition, no claim in the claim set consisting of claims 32 and 51-58 of the '705 Application renders Applicant's claim 31 unpatentable as being obvious. Claim 31 recites an insulin composition and further recites that the insulin is present at from 20% to 80% by weight in a pharmaceutical carrier material. First, claim 32 of the '705 Application recites a list of active ingredients of which insulin is but one of many possibilities. The Examiner has not established how it would have been obvious to select insulin from that list. Furthermore, even assuming it would have been obvious to select insulin the Examiner has provided no basis to support the contention that it would have been obvious to have insulin present at from 20% to 80% by weight in a pharmaceutical carrier material. Thus, there is no prima facie case of obviousness established by the Examiner.

For at least these reasons, Applicant's claim 31 is not properly rejectable under obviousness-type double patenting as being unpatentable over the claim set consisting of claims 32 and 53-58 of the '705 Application. The modification proposed by the Examiner is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. There is no evidence to suggest that this is a situation where the ordinary artisan could have modified the invention defined by claims 32 and 53-58 of the '705 Application in a manner that would result in the invention of Applicant's claim 31, and there is no evidence to suggest the artisan would have seen the benefit in doing so. Furthermore, Applicant has unexpectedly found that the invention as defined in Applicant's claim 31 provides for the pulmonary delivery of insulin in a way that can be an effective alternative to administration by subcutaneous injection, as discussed, for example on page 4 lines 32-37 in the specification. Thus, Applicant's claim 31 is allowable over claims 32 and 53-58 of the '705 Application.

C. Claim 31 vis-à-vis independent claim 33 of the '705 Application

A side-by-side tabular comparison of Applicant's claim 31 and independent claim 33 and the claims depending therefrom in the '705 Application is provided:

Applicant's claim	'705 Application
31. An **insulin** composition for pulmonary delivery, said composition comprising a dry powder of individual particles which include **insulin present at from 20% to 80% by weight** in a pharmaceutical carrier material, wherein the particles have an average size below 10 μm. (Emphasis added to highlight limitations not recited in compared claims).	33. A therapeutic composition in dry powder form comprising a therapeutically effective amount of a pharmaceutical agent in combination with a pharmaceutically acceptable carrier, wherein said carrier is a bulking agent in the form of an amorphous powder, said therapeutic composition is a powder suitable for administration by inhalation, the pharmaceutical agent is selected from the group consisting of calcitonin, erythropoietin, Factor IX, granulocyte colony stimulating factor, granulocyte macrophage colony stimulating factor, growth hormone, heparin, insulin, interferon α, interferon β, interferon δ, interleukin-2, luteinizing hormone releasing hormone, somatostatin analog, vasopressin analog, amylin, ciliary neurotrophic factor, growth hormone releasing factor, insulin-like growth factor, insulinotropin, interleukin-1 receptor antagonist, interleukin-3, interleukin-4,

	interleukin-6, macrophage colony stimulating factor, nerve growth factor, parathyroid hormone, somatostatin analog, thymosin alpha 1, Iib/IIIa inhibitor, α-1 antitrypsin, anti-RSV antibody, cystic fibrosis transmembrane regulator (CFTR) gene, bactericidal/permeability increasing protein, anti-CMVantibody, interleukin-1 receptor, pentamidine isethiouate, albuterol sulfate, metaproterenolsulfate, beclomethasone diprepionate, trimcinoline acetomide, budesonide acetonide, ipratroprium bromide, flunisolide, cromolyn sodium and ergotamine tartrate, and said powder comprises particles having a diameter less than about 10 μm and said pharmaceutical agent is available in said particles for rapid dissolution in fluid.
	35. The composition according to claim 33, wherein said powder comprises particles having a diameter of between 1 and 5 μm.
	36. The composition according to claim 33, wherein said carrier is a carbohydrate.
	37. The composition according to claim 33, wherein the pharmaceutically acceptable carrier is a monosaccharide selected from the group consisting of galactose, D-mannose, and sorbose.
	38. The composition according to claim 33, wherein the pharmaceutically acceptable

	carrier is a disaccharide selected from the group consisting of lactose and trehalose.
	39. The composition according to claim 33, wherein the pharmaceutically acceptable carrier is a disaccharide selected from the group consisting of raffinose, maltodextrins and dextran.
	40. The composition according to claim 33, wherein said carrier is an alditol selected from the group consisting of mannitol and xylitol.
	41. The composition according to claim 33, wherein the composition is spray dried.
	42. The composition according to claim 33, wherein the carrier is combined with the pharmaceutical agent prior to being spray-dried.

No claim in the claim set consisting of claims 33 and 35-42 of the '705 Application anticipates Applicant's claim 31. As can be seen from the above table, Applicant's claim 31 recites features that are not present in a claim in the above claim set. For example, Applicant's claim 31 recites "insulin present at from 20% to 80% by weight in a pharmaceutical carrier material." Independent claim 33 and the claims depending therefrom in the '705 Application fail to recite at least this feature and therefore fail to anticipate claim 31.

In addition, no claim in the claim set consisting of claims 33 and 35-42 of the '705 Application renders Applicant's claim 31 unpatentable as being obvious. Claim 31 recites an insulin composition and further recites that the insulin is present at from 20%

to 80% by weight in a pharmaceutical carrier material. First, claim 33 of the '705 Application recites a list of active ingredients of which insulin is but one of many possibilities. The Examiner has not established how it would have been obvious to select insulin from that list. Furthermore, even assuming it would have been obvious to select insulin the Examiner has provided no basis to support the contention that it would have been obvious to have insulin present at from 20% to 80% by weight in a pharmaceutical carrier material. Thus, there is no prima facie case of obviousness established by the Examiner.

For at least these reasons, Applicant's claim 31 is not properly rejectable under obviousness-type double patenting as being unpatentable over the claim set consisting of claims 33 and 35-42 of the '705 Application. The modification proposed by the Examiner is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. There is no evidence to suggest that this is a situation where the ordinary artisan could have modified the invention defined by claims 33 and 35-42 of the '705 Application in a manner that would result in the invention of Applicant's claim 31, and there is no evidence to suggest the artisan would have seen the benefit in doing so. Furthermore, Applicant has unexpectedly found that the invention as defined in Applicant's claim 31 provides for the pulmonary delivery of insulin in a way that can be an effective alternative to administration by subcutaneous injection, as discussed for example on page 4 lines 32-37 in the specification. Thus, Applicant's claim 31 is allowable over claims 33 and 35-42 of the '705 Application.

II. Independent claim 39 is allowable over the '705 Application

The Examiner's improper rejection of claim 39 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of the '705 Application should also be withdrawn.

Independent claim 39 is not anticipated by or rendered unpatentable as being an obvious variant of any of the claims in the '705 Application. Claim 39 is to an insulin

composition for pulmonary delivery, said composition comprising: a dry powder of individual amorphous particles including both insulin and a pharmaceutical carrier, wherein the particles comprise from 20% to 80% insulin by weight, have an average particle size below 10 μm, and have a moisture content below 10%. The claim set consisting of claims 28, 29 and 43-49 of the '705 Application does not define an invention that is an insulin composition and does not define an invention wherein particles comprise from 20% to 80% insulin by weight. The claim set consisting of claims 32 and 51-58 and the claim set consisting of claim 33 and 35-42 do not clearly define an invention that is an insulin composition and do not define an invention wherein particles comprise from 20% to 80% insulin by weight. In addition, the Examiner has not established a prima facie case of obviousness in that there has been no suggestion as to how one of ordinary skill in the art would have found it obvious to modify the invention defined in the '705 Application in a manner that would result in the invention of independent claim 39.

III. The dependent claims are also allowable over the '705 Application

Claims 32-34 depend from claim 31 and claims 40-43 depend from claim 39. Since the independent claims are not properly rejectable under the doctrine of obviousness-type double patenting, the claims depending therefrom are also not properly rejectable. Thus, Applicant's requests withdrawal of the rejection of each of claims 31-34 and 39-43.

Claim rejections under doctrine of Double Patenting - the '706 Application

The Examiner provisionally rejected claims 31-34 and 39-43 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26-43 of U.S. Patent Application No. 10/245,706 (hereinafter the '706 Application).

The Examiner should withdraw the provisional rejection of claims 31-34 and 39-43 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-43 of the '706 Application.

Since the present case is otherwise in condition for allowance, the present case should be allowed to issue and the double patenting issue should be taken up in the pending '706 Application. The present claims are otherwise in condition for allowance for the reasons described herein. Accordingly, the present case should be allowed to issue. To require Applicant to file a terminal disclaimer in the present case would require speculation as to the claims that will eventually issue in the '706 Application. If it turns out that the claims resulting from the '706 Application are patentably distinct from the present claims, then Applicant would have been unduly and unfairly required to submit the disclaimer.

Applicant notes that the present application and the '706 Application were both filed on the same day (i.e. they both have the same effective filing date). Thus, there is no timewise extension of the patent term with which to be concerned, and since there is no "later-filed application" the MPEP §800, which was previously relied on by the Examiner, should not prevent allowance of the present Application.

For at least these reasons, the rejections of claims 31-34 and 39-43 based on the '706 Application should be withdrawn.

Claim rejections under doctrine of Double Patenting - Eljamal et al

The Examiner rejected claims 31-34 and 39-43 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 and 13-16 of U.S. Patent 6,358,530 to Eljamal et al (hereinafter Eljamal et al) in view of U.S. Patent 5,364,838 to Rubsamen (Rubsamen).

I. Independent claim 31 is allowable over the claims of Eljamal et al and Rubsamen

The Examiner's improper rejection of claim 31 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 and 13-16 of Eljamal et al and Rubsamen should be withdrawn.

The issuance of present claim 31 would not result in an unjustified extension of a patent term. The nonstatutory obviousness-type double patenting rejection is a judicially-created doctrine seeking to prevent the unjustified timewise extension of a patent. The present application has an effective filing date of March 7, 1994. Eljamal et al has an effective filing date of April 14, 1995 which is later than the effective filing date of the present application. Thus, a terminal disclaimer in the present case would not result in the prevention of an unjustified timewise extension.

In addition, a nonstatutory obviousness-type double patenting rejection of claim 31 would not be appropriate if claim 31 is neither anticipated by, nor would have been obvious over, a claim in the later-filed Eljamal et al patent.

A side-by-side tabular comparison of Applicant's claim 31 and the claims in Eljamal et al is provided:

Applicant's claim	Eljamal et al
31. An **insulin** composition for pulmonary delivery, said composition comprising a dry powder of individual particles which include **insulin present at from 20% to 80% by weight** in a pharmaceutical carrier material, wherein the particles have an average size below 10 μm. (Emphasis	1. A spray-dried dispersible powdered composition suitable for inhalation by a human subject, comprising: (a) a therapeutically effective amount of an active agent suitable for treating a condition in said subject by inhalation; (b) a pharmaceutically acceptable excipient

added to highlight limitations not recited in compared claims).	selected from the group consisting of carbohydrates and amino acids; and (c) a dispersibility-enhancing amount of a physiologically-acceptable, water-soluble polypeptide.
	2. The composition of claim 1 wherein the excipient is a carbohydrate.
	3. The composition of claim 2, wherein said carbohydrate is selected from the group consisting of monosaccharides, disaccharides, trisaccharides, and polysaccarides.
	4. The composition of claim 3, wherein said carbohydrate is a monosaccharide selected from the group consisting of dextrose, galactose, mannitol, D-mannose, sorbitol, and sorbose.
	5. The composition of claim 3, wherein said excipient is a disaccharide selected from the group consisting of lactose, maltose, sucrose, and trehalose.
	6. The composition of claim 1 wherein the excipient is an amino acid.
	7. The composition of claim 6 wherein the amino acid is a hydrophobic amino acid.
	8. The composition of claim 7 wherein the hydrophobic amino acid is selected from the group consisting of alanine, isoleucine, leucine, methionine, phenylalanine,

	proline, tryptophan, and valine.
	9. The composition of claim 6 wherein the amino acid is a polar amino acid.
	10. The composition of claim 9 wherein the amino acid is selected from the group consisting of arginine, histidine, lysine, cystine, glycine, glutamine, serine, threonine, tyrosine, aspartic acid and glutamic acid.
	11. The composition of claim 1 wherein the excipient is present in an amount of about 50% by weight to about 99.9% by weight.
	13. The composition of claim 1 comprising particles having a mass median diameter (MMD) of less than 10 microns.
	14. The composition of claim 13 comprising particles having a mass median diameter of less than 5 microns.
	15. The composition of claim 1 comprising particles having a mass median aerodynamic diameter (MMAD) of less than 5 microns.
	16. The composition of claim 1, wherein said active agent is selected from the group consisting of steroids, bronchdilators, mast cell inhibitors, antibiotics, polypeptides and nucleic acids.

No claim in Eljamal et al renders Applicant's claim 31 unpatentable. As can be seen from the above table, Applicant's claim 31 recites features that are not present in a claim in the above claim set. For example, Applicant's claim 31 recites an "insulin composition" and further recites "insulin present at from 20% to 80% by weight in a pharmaceutical carrier material." The claims of Eljamal et al fail to recite at least these features and therefore fail to anticipate claim 31.

In addition, no claim in Eljamal et al renders Applicant's claim 31 unpatentable as being obvious. Applying the 35 U.S.C. §103 style of analysis, Applicant's claim 31 is not rendered unpatentable by the invention defined in any of the claims in Eljamal et al. Claim 31 recites an insulin composition and further recites that the insulin is present at from 20% to 80% by weight in a pharmaceutical carrier material. These features are not present in the invention defined by the claims of Eljamal et al. Since these features are not present and since the Examiner has provided no basis for making a modification that would result in the invention defined by Applicant's claim 31, there is no prima facie case established.

The Examiner's contention in the Office Action (see page 6) that the Eljamal et al claims render Applicant's claim 31 unpatentable because Rubsamen teaches the use of the polypeptide insulin is not with merit and does not serve to further the Examiner's position. A " a dispersibility-enhancing amount of a physiologically-acceptable, water-soluble polypeptide" as recited in Eljamal et al's claim 1 does not anticipate the "insulin composition" limitation in Applicant's claim 31 and does not anticipate the "insulin present at from 20% to 80% by weight in a pharmaceutical carrier material" limitation in Applicant's claim 31. Further, the Examiner has failed to provide any reason as to why it would have been obvious to use insulin as the active agent in the Eljamal formulation. Still further, the Examiner has failed to provide any reason as to why it would have been obvious to use the recited amount of insulin.

For at least these reasons, Applicant's claim 31 is not properly rejectable under obviousness-type double patenting as being unpatentable over the claims of Eljamal et

al. The modification to the invention defined by the claims of Eljamal et al that would be necessary to arrive at the invention of Applicant's claim 31 is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. There is no evidence to suggest that this is a situation where the ordinary artisan could have modified the invention defined by the claims of Eljamal et al in a manner that would result in the invention of Applicant's claim 31, and there is no evidence to suggest the artisan would have seen the benefit in doing so. Thus, Applicant's claim 31 is allowable over the claims of Eljamal et al.

II. Independent claim 39 is also allowable over the claims of Eljamal et al and Rubsamen

The Examiner's improper rejection of claim 39 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 and 13-16 of Eljamal et al in view of Rubsamen should be withdrawn.

The issuance of present claim 39 would not result in an unjustified extension of a patent term. The nonstatutory obviousness-type double patenting rejection is a judicially-created doctrine seeking to prevent the unjustified timewise extension of a patent. The present application has an effective filing date of March 7, 1994. Eljamal et al has an effective filing date of April 14, 1995 which is later than the effective filing date of the present application. Thus, a terminal disclaimer in the present case would not result in the prevention of an unjustified timewise extension.

In addition, a nonstatutory obviousness-type double patenting rejection of claim 39 would not be appropriate if claim 39 is neither anticipated by, nor would have been obvious over, a claim in the later-filed Eljamal et al patent, even in view of Rubsamen.

A side-by-side tabular comparison of Applicant's claim 39 and the claims in Eljamal et al is provided:

Applicant's claim	Eljamal et al
39. An **insulin composition** for pulmonary delivery, said composition comprising: a dry powder of individual **amorphous particles** including both **insulin** and a pharmaceutical carrier, wherein the particles **comprise from 20% to 80% insulin by weight**, have an average particle size below 10 μm, and have a **moisture content below 10%**. (Emphasis added to highlight limitations not recited in compared claims).	1. A spray-dried dispersible powdered composition suitable for inhalation by a human subject, comprising: (a) a therapeutically effective amount of an active agent suitable for treating a condition in said subject by inhalation; (b) a pharmaceutically acceptable excipient selected from the group consisting of carbohydrates and amino acids; and (c) a dispersibility-enhancing amount of a physiologically-acceptable, water-soluble polypeptide.
	2. The composition of claim 1 wherein the excipient is a carbohydrate.
	3. The composition of claim 2, wherein said carbohydrate is selected from the group consisting of monosaccharides, disaccharides, trisaccharides, and polysaccarides.
	4. The composition of claim 3, wherein said carbohydrate is a monosaccharide selected from the group consisting of dextrose, galactose, mannitol, D-mannose, sorbitol, and sorbose.
	5. The composition of claim 3, wherein said excipient is a disaccharide selected from the group consisting of lactose,

	maltose, sucrose, and trehalose.
	6. The composition of claim 1 wherein the excipient is an amino acid.
	7. The composition of claim 6 wherein the amino acid is a hydrophobic amino acid.
	8. The composition of claim 7 wherein the hydrophobic amino acid is selected from the group consisting of alanine, isoleucine, leucine, methionine, phenylalanine, proline, tryptophan, and valine.
	9. The composition of claim 6 wherein the amino acid is a polar amino acid.
	10. The composition of claim 9 wherein the amino acid is selected from the group consisting of arginine, histidine, lysine, cystine, glycine, glutamine, serine, threonine, tyrosine, aspartic acid and glutamic acid.
	11. The composition of claim 1 wherein the excipient is present in an amount of about 50% by weight to about 99.9% by weight.
	13. The composition of claim 1 comprising particles having a mass median diameter (MMD) of less than 10 microns.
	14. The composition of claim 13 comprising particles having a mass median diameter of less than 5 microns.
	15. The composition of claim 1 comprising particles having a mass median aerodynamic diameter (MMAD) of less

	than 5 microns.
	16. The composition of claim 1, wherein said active agent is selected from the group consisting of steroids, bronchdilators, mast cell inhibitors, antibiotics, polypeptides and nucleic acids.

No claim in Eljamal et al renders Applicant's claim 39 unpatentable. As can be seen from the above table, Applicant's claim 39 recites features that are not present in a claim in the claim set. For example, Applicant's claim 39 recites an "insulin composition" and further recites "wherein the particles comprise from 20% to 80% insulin by weight." These features are not claimed by Eljamal et al. Furthermore, Applicant's claim 39 recites "a dry powder of individual amorphous particles" and "a moisture content below 10%." These features are also not claimed by Eljamal et al.

In addition, no claim in Eljamal et al renders Applicant's claim 39 unpatentable as being obvious, even when taken with Rubsamen. The insulin composition, the amount of insulin present, the amorphous particles, and the dryness of the particles are not defined by the claims of Eljamal et al. Rubsamen fails to cure these deficiences. Since these features are not present and since the Examiner has provided no basis for making a modification that would result in the invention defined by Applicant's claim 31, there is no prima facie case of obviousness established.

For at least these reasons, Applicant's claim 39 is not properly rejectable under obviousness-type double patenting as being unpatentable over the claims of Eljamal et al in view of Rubsamen. The modification to the invention defined by the claims of Eljamal et al that would be necessary to arrive at the invention of Applicant's claim 39 is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. There is no evidence to suggest that this is a situation where the ordinary artisan could have modified the invention defined by the claims of

Eljamal et al in a manner that would result in the invention of Applicant's claim 39, and there is no evidence to suggest the artisan would have seen the benefit in doing so. Thus, Applicant's claim 39 is allowable over the claims of Eljamal et al.

III. The dependent claims are also allowable over Eljamal et al and Rubsamen

Claims 32-34 depend from claim 31 and claims 40-43 depend from claim 39. Since the independent claims are not properly rejectable under the doctrine of obviousness-type double patenting based on Eljamal et al and Rubsamen, the claims depending therefrom are also not properly rejectable. Thus, Applicant requests withdrawal of the rejection of each of claims 31-34 and 39-43.

Claim rejections under doctrine of Double Patenting - Patton et al

The Examiner rejected claims 31-34 and 39-43 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 and 13-16 of U.S. Patent 5,997,848 to Patton et al. Applicant will submit a terminal disclaimer in compliance with 37 CFR 1.321(c) in accordance with the Examiner's suggestion upon the indication that the claims are otherwise allowable.

New Claims

Claims 44-50 have been added to define other aspects of Applicant's invention. The new claims are not intended as further limitations of previous claims and are not being added for reasons related to patentability.

Conclusion

The claims are allowable for the reasons given above. Thus, the Examiner is respectfully requested to reconsider the present rejections and allow the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

JANAH & ASSOCIATES

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